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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,079	02/16/2000	Gail M. Clinton	49321-1A	5713

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/506,079	CLINTON ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8-10,18-20 and 38-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 8-10, 18-20, 38-44 and 46-48* is/are rejected.

7)☒ Claim(s) *45 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 12/14/2006 is acknowledged.

Claims 1-3, 8-10, 18-20 and 38-49 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections Withdrawn:

3. The rejection of claims 38, 39, 45 and 49 under 35 U.S.C. 102(b) as being anticipated by Sigma Chemical Company (Sigma Chemical Company Catalog, 1989, pages 914, 918, 1171, and 1243) is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained and New Grounds of Rejection/Objection:

4. Claims 44, 45, 48 and 49 are objected to for phrases such as "polypeptide consisting of SEQ ID NO: 14" or "polypeptide comprises SEQ ID NO: 15", for example. These claims should be amended to recite "polypeptide consisting of the amino acid sequence of SEQ ID NO: 14" or "polypeptide comprises the amino acid sequence of SEQ ID NO: 15" , for example.

5. Claims 1-3, 8-10, 18-20, 38-44, 46-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the use of the term "polymorphic" or "polymorphism-comprising fragments" or "respective polymorphic amino acid positions" because it appears from the remarks that applicants intend that these phrases identify the residue in the Xaa positions of the listed sequences to be a residue that is different from what is found in the most commonly found sequence. However, the term "polymorphism" refers to a position in a sequence that is found to be altered in nature, but does not serve to identify the residue at that position.

6. Claims 1, 2, 18-20, 42 and 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained to present new grounds of rejection. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the amendment filed 12/14/2006 introduces new matter into the specification as originally filed.

The claims have been amended to recite the limitation "wherein the fragments comprise the respective polymorphic amino acid positions of the corresponding SEQ ID NOS: 14 and 19-28" or "polymorphism-comprising fragments". This introduces new matter into the specification. Applicants point to support in the specification at Table 1 and also in the original claim 27, which recited "ECDIIA variant sequence". These passages of the originally filed disclosure do not provide adequate support for the amendment. Table 1 discloses variant sequences and identifies the positions of the herstatin sequence that are polymorphic with respect to most commonly found sequence. The term "ECDIIIa variant" appears to refer to variants that

comprise the C-terminal 79 amino acid fragment of herstatin and comprise substitutions at certain amino acid positions as defined in Table 1. However, the phrase "wherein the fragments comprise the respective polymorphic amino acid positions of the corresponding SEQ ID NOS: 14 and 19-28" is interpreted to mean that the fragments are limited to those sequences that encompass the positions defined in Table 1 as polymorphic. Thus, a subgenus of fragments appears to have been carved out so that fragments not encompassing these positions will be excluded from the scope of the claims. There is no support in the specification or claims as originally filed for the concept of such a subgenus. The specification teaches fragments taken from anywhere in the C-terminal 79 amino acids of any of SEQ ID NOS: 14 and 19-28 or SEQ ID NOS: 15 and 29-38. The specification teaches fragments having the size of about 50 to about 79 amino acids in length or about 69-79 amino acids in length. The specification does not provide further characterization of the fragments to be taken from the C-terminal 79 amino acids of any of SEQ ID NOS: 14, 15 and 19-38. Therefore, applicants do not appear to have been in possession of the inventions as they are now claimed.

Please note that this rejection is not applied to claims 8, 41 and 46, which contain the phrase "polymorphism-comprising fragments" and also the phrase "wherein the fragments comprise the respective polymorphic amino acid positions" because these claims are drawn to fragments of at least 80 amino acids in length, wherein the C-terminal 79 amino acids are present from SEQ ID NOS: 15 and 29-38. Because the C-terminal 79 amino acids are present and because the polymorphisms are only found in the C-terminal 79 amino acids of SEQ ID NOS: 15 and 29-38, these fragments inherently are "polymorphism-comprising" fragments.

7. Claims 1, 18, and 19 remain rejected under 35 U.S.C. 102(a) as being anticipated by Doherty-I (Proc. Natl. Acad. Sci., USA, 96: 10869-10874, 1999, September; of record).

Claims 1, 18, and 19 do not receive benefit of priority to the parent application, 09/234,208, because SEQ ID NOS: 14, and 19-28 are not found in the parent application. Therefore, the filing date of the instant application is used for comparison with the prior art (2/16/2000). New grounds of rejection are presented.

The claimed polypeptides and pharmaceutical compositions are drawn to polypeptides comprising the amino acid sequence selected from the group consisting of polymorphic SEQ ID NOS: 14 and 19-28, and polymorphism-comprising fragments thereof of about 50-79 contiguous residues in length, wherein the fragments comprise the respective polymorphic amino acid positions of the corresponding SEQ ID Nos: 14 and 19-28. The phrase "polymorphism-comprising fragment" is interpreted to mean that the fragment comprises an Xaa residue, but is not interpreted to identify the Xaa residue, or that the fragment comprises a position that has been identified in the specification to be one where a polymorphism can occur.

The present specification provides SEQ ID NOS: 14 and 19-28, which are the C-terminal 79 amino acid sequences of SEQ ID NOS: 15 and 29-38, respectively. The amino acid sequences of SEQ ID NOS: 14 and 19-28 contain residues identified as "Xaa", with the exception of SEQ ID NO: 14. The specification teaches that the sequence of SEQ ID NO: 14 (identified in the specification as the "most commonly detected sequence" and shown in Figure 8) differs from the herstatin sequence of Doherty-I (supra) at residues 6 and 73. Between residues 6 and 73, herstatin and SEQ ID NO: 14 are identical in sequence. Each of SEQ ID NOS: 19-28 contains Xaa residues where most of these residues are defined as one of two residues,

where one of the choices is a residue that is found in the sequence of Doherty-I (supra). The phrase "polymorphism-comprising fragment" is interpreted to mean that the fragment comprises an Xaa residue, but is not interpreted to identify the Xaa residue. Therefore, a "polymorphism comprising fragment" may have a sequence that is the same as that found in the Doherty-I sequence. Because the claims are drawn to polypeptides comprising polymorphism-comprising fragments of about 50 to 79 contiguous residues in length, the claims read on comprising subsequences of any of SEQ ID NOS: 19-28. In the sequences of SEQ ID NOS: 19-28, it is possible to find fragments of about 50 amino acids in length that would have the same sequence as a fragment found in the sequence of Doherty-I (supra) even when weight is given in the consideration of the limitation that the "fragments comprise the respective polymorphic amino acid positions" because the recitation "polymorphic amino acid position" fails to limit the residue at the polymorphic position to the residue that is not found in Doherty-I due to the fact that each of SEQ ID NOS: 19-28 comprise amino acids identified as "Xaa", where the amino acid may be that of the variant, or may be that of the most common position. Further, because the claims are drawn to polypeptides that comprise these subsequences (fragments of at least 50 to 79 amino acids in length), the claimed polypeptides read on the full-length herstatin that is described in Doherty-I. Please note that SEQ ID NO: 14 is not included in this analysis because SEQ ID NO: 14 comprises polymorphic amino acid positions that are defined (a proline at position 6 and an aspartate at position 73), and a fragment encompassing these positions would not be same as that found in Doherty-I (supra).

8. Claims 1, 18, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Doherty-II (U.S. 6,414,130; published Jul. 2, 2002; effective filing date Jan. 20, 1999; of record)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Doherty discloses SEQ ID NO: 1 and SEQ ID NO: 2, which are the amino acid sequences of Herstatin and its C-terminal 79 amino acid fragment. Each of SEQ ID NOS: 19-28 contains Xaa residues where most of these residues are defined as one of two residues, where one of the choices is a residue that is found in the sequence of Doherty-II (supra). The phrase "polymorphism-comprising fragment" is interpreted to mean that the fragment comprises an Xaa residue, but is not interpreted to identify the Xaa residue. Therefore, a "polymorphism comprising fragment" may have a sequence that is the same as that found in the Doherty-II sequence. Because the claims are drawn to polypeptides comprising polymorphism-comprising fragments of about 50 to 79 contiguous residues in length, the claims read on comprising subsequences of any of SEQ ID NOS: 19-28. In the sequences of SEQ ID NOS: 19-28, it is possible to find fragments of about 50 amino acids in length that would have the same sequence as a fragment found in the sequence of Doherty-II (supra) even when weight is given in the consideration of the limitation that the "fragments comprise the respective polymorphic amino acid positions" because the recitation "polymorphic amino acid position" fails to limit the

residue at the polymorphic position to the residue that is not found in Doherty-II due to the fact that each of SEQ ID NOS: 19-28 comprise amino acids identified as "Xaa", where the amino acid may be that of the variant, or may be that of the most common position. Further, because the claims are drawn to polypeptides that comprise these subsequences (fragments of at least 50 to 79 amino acids in length), the claimed polypeptides read on the full-length herstatin that is described in Doherty-II or the C-terminal 79 amino acid fragment that comprises a 50 amino acid subsequence that is in common with an 50 amino acid subsequence of any of SEQ ID NOS: 19-28. Please note that SEQ ID NO: 14 is not included in this analysis because SEQ ID NO: 14 comprises polymorphic amino acid positions that are defined (a proline at position 6 and an aspartate at position 73), and a fragment encompassing these positions would not be same as that found in Doherty-II (supra). Doherty also teaches compositions where herstatin is combined with a monoclonal antibody that binds to the extracellular domain of Her-2 (claim 20). Therefore, Doherty-II teaches polypeptides and compositions that are the same as that claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, and 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-10, 18-20, 27, 28, 29, and 30 of copending Application No. 09/234,208. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sequences of SEQ ID NO: 1 or SEQ ID NO: 2 of copending application no. 09/234,208 are sequences that comprise fragments that are subsequences of claims 1 and 18-20 of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed. Claims 45 and 49 are objected to as indicated above, but are otherwise allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
March 19, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER